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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	Case No. 18-CR-00258 EJD UNITED STATES' OPPOSITION TO DEFENDANT ELIZABETH HOLMES'S MOTION TO EXCLUDE EXPERT TESTIMONY OR, IN THE ALTERNATIVE, COMPEL ADEQUATE RULE 16 DISCLOSURE Date: July 20, 2020 Time: 1:30 p.m.

INTRODUCTION

The doctors whose testimony Defendant Holmes seeks to exclude in her motion are not primarily expert witnesses. As the government explained in its Rule 16 notice, these doctors are all fact / percipient witnesses who will testify about their own personal observations and experiences with patients who received inaccurate Theranos blood tests. The government anticipates that there will be minimal testimony from these witnesses that arguably falls under Federal Rule of Evidence 702 and any such testimony will be made within the context of their percipient witness testimony, and will be

supported through proper foundation. The government has produced in discovery the relevant memoranda of interview (MOIs) for these doctors and their respective patients. The government nevertheless provided notice of those portions of the doctors' anticipated testimony that might arguably fall under Rule 702, and also provided the defense with a brief description of the doctors' education, credentials, and professional background. Between the government's notice and the discovery produced in this case, the government has more than met its obligations under Rule 16. The Court should deny the motion.

FACTUAL BACKGROUND

Drs. Steven Linnerson, Audra Zachman, Edward Szmuc, John Couvaras, Gerald Asin, Curtis Page, and Ms. JoEllen Embry each treated patients who received inaccurate results from Theranos blood tests. The government has provided MOIs for each of these doctors, as well as any and all reports for their respective patients, which detail the doctors' accounts of referring their patients to Theranos for specific tests and thereafter learning about the inaccurate blood test results. The government—in an abundance of caution—also provided Rule 16 notice for any statements that the doctors provided during these interviews that drew on their knowledge, skill, experience, training, and education as treating physicians, and therefore might arguably fall under Rule 702.

I. Dr. Linnerson

Dr. Linnerson became aware of problematic hCG test results from Theranos through patient B.G.'s case. (Decl. of Vanessa Baehr-Jones (Baehr-Jones Decl.), Exh. 1, 6/13/19 Linnerson MOI, at 3.) While receiving treatment at Dr. Linnerson's clinic, B.G. received a Theranos hCG test that showed her hCG levels were going down, which she thought meant she was experiencing yet another miscarriage. (*Id.*) But the Theranos test was wrong; B.G. was pregnant. (*Id.*) Dr. Linnerson explained to the federal agent during his interview that the Theranos hCG tests which clinicians in his practice were reviewing "were wild throws outside what [they] were used to seeing, outside [their] collective experience as a group of 20 clinicians." (*Id.*) As the MOI documents, Dr. Linnerson has 31 years of experience as an OBGYN, and had been ordering hCG tests for approximately ten years before he started using Theranos for patient tests. He estimated that he had ordered around 5,000 hCG tests over the course of this career. Based on the discrepancies he and his colleagues were noting, the clinic decided to conduct a small

study comparing their patients' Theranos hCG results with results from Sonora Quest and LabCorp. (*Id.*) Ultimately, Theranos's performance in the study failed to restore confidence in the accuracy and reliability of the company's tests, causing the clinic to cease referring patients to Theranos for hCG tests. (*Id.*)

The government noticed Dr. Linnerson as "a fact / percipient witness, whose testimony may also cover topics and/or opinions informed by his knowledge, skill, experience, training, and education." The notice referenced Dr. Linnerson's understanding as a trained and experienced OBGYN of the hCG test and how to interpret hCG values, since his expertise in this area might be relevant as part of his testimony about treating B.G. and the actions he and his clinic took in response to receiving inaccurate hCG results from Theranos.

II. Dr. Zachman

Dr. Zachman, who holds a doctorate degree in nursing, also treated patient B.G. and worked in the same clinic as Dr. Linnerson. (Baehr-Jones Decl., Exh. 2, Zachman MOI, at 1.) As part of her role on the product committee for the clinic, she received promotion materials for Theranos's services from a Theranos sales representative. (*Id.*) According to Dr. Zachman, Theranos represented that their blood tests were valid, less expensive, and that they were able to use less blood and that it was more convenient. (*Id.* at 2.)

During her interview with the government, Dr. Zachman reviewed the patient records for B.G. and explained what the hCG levels in the Theranos tests meant based on her experience: that B.G. was no longer pregnant. (*Id.*) Dr. Zachman explained that she then reached out to B.G. to prepare her that her pregnancy was lost. (*Id.*) After this difficult conversation, though, Dr. Zachman ordered further testing to confirm the miscarriage, since this fourth miscarriage would have placed B.G. in a category called "recurrent pregnancy loss." (*Id.* at 3.) Dr. Zachman was surprised to discover that the resulting tests showed B.G. was, in fact, still pregnant. (*Id.*) This caused her confusion and embarrassment, and ultimately resulted in her losing trust in Theranos tests. (*Id.*) She explained that if she had relied on the Theranos' result and initiated the treatment protocol for a miscarriage, it is very likely she would have terminated a viable pregnancy. (*Id.*) After this experience with B.G., Dr. Zachman called Theranos to speak with their complaint department and sent emails to Theranos to report the inaccurate result. (*Id.*)

She also worked with Dr. Linnerman and others in the clinic to conduct the small study of Theranos hCG results in order to determine whether they could continue using Theranos. (*Id.*)

In addition to all of the above information, which was documented in the Zachman MOI, the government provided Rule 16 notice for Dr. Zachman regarding her knowledge and experience with respect to hCG testing, since—similar to Dr. Linnerson—her expertise in this area might be relevant as part of her testimony about treating B.G. The notice also provided information concerning Dr. Zachman's education, credentials, and professional experience.

III. Dr. Szmuc

Dr. Szmuc also worked in the same OBGYN practice as Dr. Linnerson and Dr. Zachman. (Baehr-Jones Decl., Exh. 3, Szmuc MOI, at 1.) Now retired, he began practicing in 1983. (*Id.*) Dr. Szmuc recalled hearing about Theranos from a sales representative who visited their practice and told him that Theranos' tests were accurate. (*Id.*) Over time, Dr. Szmuc began referring a large portion of his patients to Theranos because of the ease of the fingerstick test. (*Id.* at 2.) He estimated that he saw between 30-40 patients per day, and referred approximately 10-15 of those patients to Theranos. (*Id.*) However, Dr. Szmuc began to receive hCG results from Theranos tests that he doubted. (*Id.*) As he explained during his interview, the hCG levels he would expect to see in a normal pregnancy would first be between 1-2,000, with the values doubling every 48 to 72 hours. (*Id.*) Dr. Szmuc explained that he relies on hCG tests "immensely" to make treatment decisions during a patient's pregnancy. (*Id.*) For example, if hCG values stayed level it could indicate an ectopic pregnancy that required either a surgical or pharmaceutical intervention. (*Id.*) He recalled calling Theranos to alert them to the inaccurate test results and remembered not feeling reassured by their responses. (*Id.*) In contrast, Dr. Szmuc never had a question about the accuracy of a Sonora Quest test in the nearly 30 years that he had been using them. (*Id.*)

In addition to Dr. Szmuc's MOI summarizing the above, the government provided Rule 16 notice outlining Dr. Szmuc's explanations concerning hCG values and the meaning of various hCG test results, since his experience and knowledge of the hCG test might be relevant to his percipient witness testimony. The notice also provided information concerning Dr. Szmuc's education, credentials, and professional experience.

IV. Dr. Couvaras

Dr. Couvaras will testify about his experience treating patient G.M. who received an inaccurate hCG result from a Theranos blood test. (Baehr-Jones Decl., Exh. 4, Couvaras MOI, at 1.) Dr. Couvaras first reviewed an initial hCG test from Sonora Quest showing that G.M. was likely pregnant. (*Id.*) G.M. then repeated the test, this time through Theranos. (*Id.*) The resulting test showed an hCG value so low that Dr. Couvaras considered this to be a "chemical loss" and concluded the pregnancy was lost. (*Id.*) He then placed G.M. back on two medications she was taking before the pregnancy, including one medication, Lovastatin, which has a true contraindication for pregnancy. (*Id.* at 1-2.) When G.M. called the office later to explain that she still had not gotten her period, Dr. Couvaras ordered another test. (*Id.* at 1.) G.M. again took an hCG test through Theranos. (*Id.*) The hCG results caused Dr. Couvaras to be concerned that G.M. might be experiencing an ectopic pregnancy. (*Id.*) Only after performing an ultrasound in his office was he able to conclude that G.M. was, in fact, pregnant without complication. (*Id.*) Dr. Couvaras's office reported G.M.'s inaccurate hCG test results to Theranos, and the evidence will show that Defendant Holmes learned of the incident in an email. (*Id.*; Baehr-Jones Decl., Exh. 5, 9/29/14 Holmes Email.)

In addition to Dr. Couvaras's MOI summarizing the above, the government provided Rule 16 notice outlining Dr. Couvaras's explanations concerning hCG values and the meaning of various hCG test results, since his experience and knowledge of the hCG test might be relevant to his percipient witness testimony. The notice also provided information concerning Dr. Couvaras's education, credentials, and professional experience.

V. Ms. Embry

Ms. Embry is a nurse practitioner who has worked in the field of women's health since 1983. (Baehr-Jones Decl., Exh. 6, Embry MOI, at 1.) Her current practice covers all areas of women's health with an emphasis on endocrine problems. (*Id.*) Ms. Embry frequently treats patients who suffer from irregular periods, high testosterone levels, bald spots, acne, and facial hair—all potential symptoms of polycystic ovarian syndrome (POS). (*Id.*) After three to four months of ordering Theranos blood tests for her patients, Ms. Embry noticed problematic results. (*Id.*) Some of her patients typically experience "man levels" of testosterone, but these levels were not being reflected in the Theranos tests. (*Id.*) She

explained during her interview that a testosterone level of 30 to 40 is normal in a woman, but some of her patients typically experience levels of 120. (*Id.*) The Theranos tests, though, were showing these patients as having testosterone levels of less than one. (*Id.*) Ms. Embry also noticed that her patients' Theranos test results showed unusually high levels of calcium, which can be a sign of problems with the parathyroid gland. (*Id.* at 3.) Ms. Embry explained that before this she had been using Sonora Quest and LabCorp for approximately 20 years to conduct blood tests on her patients and had never seen these kinds of clinical errors in the lab results. (*Id.* at 1-2.)

Ms. Embry reported her concerns with her patients' blood test results to Theranos, ultimately speaking directly with Christian Holmes, Defendant Holmes's brother, who explained that the Theranos machines were not calibrated for fingerstick draws. (*Id.* at 2.) Frustrated, Ms. Embry responded that her patients were having venous draws. (*Id.*) Finally, in March 2015, Ms. Embry sent an email to Theranos warning the company that it was sending out inaccurate patient results. (*Id.* at 3.) During her interview with the government, Ms. Embry remembered waking up one Friday morning to find 1,500 Theranos lab results in her inbox. (*Id.*) The company had voided every lab result she had ever ordered. (*Id.*)

In addition to Ms. Embry's MOI summarizing the above, the government provided Rule 16 notice outlining Ms. Embry's explanations concerning testosterone values in patients suffering from POS and how to interpret testosterone and calcium values in blood tests, since her experience and knowledge of these tests might be relevant to her percipient witness testimony. The notice also provided information concerning Ms. Embry's education, credentials, and professional experience.

VI. Dr. Asin

Dr. Asin treated patient E.T. and reviewed her HIV/AIDS test results from a Theranos blood test. (Baehr-Jones Decl., Exh. 7, Asin 302, at 2.) Dr. Asin explained to the federal agent during his interview that the Theranos results did not make any sense: the test showed that the patient was reactive for HIV 1+2 antibodies, but non-reactive for HIV 1 antibody and HIV 2 antibody, separately. (*Id.*) When E.T. learned about her HIV/AIDS results from Dr. Asin, which appeared to show her test was positive, she recalled feeling "terrible" and "awful." (Baehr-Jones Decl., Exh. 8, E.T. 302, at 2.) She explained during an interview that she thought she was dying. (*Id.*) Because she was in between health insurance, she could not afford another HIV test immediately, and had to wait to "a while" for another test. (*Id.*)

Dr. Asin also remembered other patients of his who received inaccurate test results from Theranos. (Baehr-Jones Decl., Exh. 7, at 2.) Specifically, he recalled during his interview that some of his patients had uncharacteristically high PSA test results from Theranos blood tests. (*Id.*) PSA test results help detect prostate cancer, and high results may result in a doctor ordering additional invasive tests to recheck PSA levels. (*Id.*) Dr. Asin also recalled Theranos diabetic tests that did not seem as accurate, and protein and calcium tests that seemed incorrect as well. (*Id.*) It was impossible for the government to obtain all of those test results, however, because Dr. Asin kept hard copy records for his patients which were not searchable. (Decl. of Special Agent Adelaida Hernandez (Hernandez Decl.) at 1.) Thus, other than relying on Dr. Asin's memory, government investigators had no method of searching for, and obtaining, the test results for other patients of Dr. Asin who may have received inaccurate Theranos test results.[1] (*Id.*)

In addition to the Federal Bureau of Investigation (FBI) 302 reports summarizing the above, the government provided Rule 16 notice outlining Dr. Asin's explanations concerning HIV tests and how to interpret HIV antibody test results, as well as his knowledge of PSA, diabetic, calcium, and protein tests, since his experience and knowledge of these tests might be relevant to his percipient witness testimony. The notice also provided information concerning Dr. Asin's education, credentials, and professional experience.

VII. Dr. Page

Dr. Page has been practicing since 1994 with a focus on advanced chronic disease management and population health. (Baehr-Jones Decl., Exh. 10, Page 302, at 1.) Dr. Page explained during his interview with federal investigators that he was part of an Accountable Care Organization, which partnered with health care providers and vendors like Theranos. (*Id.*) Through this partnership, a

[1] The government was aware of E.T.'s test results because a complaint had been filed with Theranos about her inaccurate HIV test results. Because the government already had the specific patient name, Dr. Asin was able to locate E.T.'s physical file and find the Theranos test results there. The searchable repository containing all Theranos lab results, the Laboratory Information Systems (LIS) database, remains encrypted and inaccessible. (Baehr-Jones Decl, Exh. 9, Balwani Petition to Appeal, at 5.) Thus, the government has no ability to search for Theranos test results by doctor, by patient name, by type of blood test, etc. (*See id.*) The government must instead piece together these test results from records the patients themselves may have kept, or from records within the doctors' offices, among other piecemeal methods.

Theranos phlebotomist operated out of Dr. Page's office, providing tests to his patients. (*Id.*) Dr. Page will testify about his experience ordering A1C and CBC tests for his patients through Theranos. (A1C tests for average blood glucose levels. A complete blood count (CBC) is a blood test used to evaluate a patient's overall health and detects a wide range of disorders, including anemia, infection, and leukemia.) Dr. Page will testify that he experienced a high quantity of abnormal A1C tests with Theranos testing. (*Id.*) Dr. Page will further testify that he did not understand how Theranos could not have known they had a problem with A1Cs for months. (*Id.*) Dr. Page will testify that he did not think it would require a doctor to point out this kind of issue. (*Id.*)

In addition to the Federal Bureau of Investigation (FBI) 302 report summarizing the above, the government provided Rule 16 notice outlining Dr. Page's explanations concerning A1C tests and his conclusions about the faulty results, since his experience and knowledge of this test might be relevant to his percipient witness testimony. The notice also provided information concerning Dr. Page's education, credentials, and professional experience.

ARGUMENT

I. Rule 16 Requires Limited Expert Notice for Treating Physicians Testifying About Generic and Commonly-Used Tests

In general, treating physicians are exempted from expert notice in civil cases because they are offering their professional opinions based on their percipient knowledge and are therefore "a species of percipient witness." *See Goodman v. Staples the Office Superstore, LLC*, 644 F.3d 817, 819 (9th Cir. 2011). Treating physicians "are not specially hired to provide expert testimony; rather, they are hired to treat the patient and may testify to and opine on what they saw and did without the necessity of the proponent of the testimony furnishing a written expert report." *Id.*

The same principles apply here. The government did not hire the above doctors and medical specialists; they are involved in this case only because of the patients they treated. Accordingly, they will primarily be testifying about their own personal observations and experiences treating patients who received inaccurate Theranos test results. Similarly, their observations that they had never seen these kinds of clinical errors in their many decades of submitting tests to Sonora Quest or LabCorp are not expert opinions at all, but merely their own personal observations. This testimony therefore falls under

Federal Rule of Evidence 701(a). There is no additional Rule 16 discovery to produce concerning such observations, and Defendant Holmes already has all the materials she might use to cross-examine on this subject. To the extent Defendant Holmes believes the observations of these professionals are wrong, not supported by documents, or imprecise, she may cross examine them. Indeed, her complaints seem to go to the merits of their observations—not notice about what they will say. There is no basis in Rule 16 for exclusion.

To the extent these doctors will offer minimal testimony that arguably falls under Rule 702, these doctors and medical professionals fall into the category of expert witnesses who are "so 'generic' and routine (such as a DEA laboratory chemist) that the testimony will be largely predictable." *United States v. Cerna*, No. CR 08–0730 WHA, 2010 WL 2347406, at *1 (N.D. Cal. June 8, 2010) (quoting the Advisory Committee Notes to the 1993 Amendment to Rule 16(a)(1)(G)). This category of expert witnesses requires only a "generic description of the likely witness and that witness's qualifications." Fed. R. Crim. P. 16, Advisory Comm. Notes (1993 Amendment).

For instance, Drs. Linnerson, Zachman, Szmuc, and Couvaras will not be presenting any novel opinions concerning hCG tests, but will merely be explaining what the values for these tests mean based on their education and training as medical professionals. There is nothing "new or controversial" about this testimony: the values from these test results and their meanings are commonly known in the field and not the subject of dispute between the parties. *See* Fed. R. Crim. P. 16, Advisory Comm. Notes (1993 Amendment) (explaining that Rule 16 notice is "particularly important if the expert is expected to testify on matters which touch on new or controversial techniques or opinions"). The same applies for Dr. Asin's testimony concerning HIV antibody tests, Ms. Embry's testimony about testosterone levels, and Dr. Page's testimony about A1C tests. These are all common tests, the results of which doctors routinely analyze. Nothing in these witnesses' expected testimony will present novel or controversial opinions that might be the subject of a *Daubert* hearing.

II. The Government's Produced Discovery and Rule 16 Notice Are Sufficient

The government has provided all the relevant discovery in its custody and control relating to the doctor witnesses, as well as their patients, in the form of MOIs, 302s, and attached documents. As set forth in the facts section above, this discovery provides a thorough account of the government interviews

with each of the doctors, during which the witnesses recounted their experiences treating patients who received inaccurate Theranos test results. In its Rule 16 notice, the government has further provided Defendant Holmes with the names of the specific tests the treating doctors will be discussing in their direct testimony, as well as the doctors' education, credentials, and professional experience. This notice is sufficient to alert the defense to which tests each doctor witness will discuss and gives the defense the ability to cross-examine the treating doctors about those tests, as well as about their background and experience. This is all that Rule 16 requires for such expert witnesses, who will be presenting only "generic" expert testimony, and who will primarily be testifying as percipient witnesses.

The government will continue to produce any new discovery and will timely turn over any additional MOIs, 302s, and/or relevant documents that are created during trial preparation.

CONCLUSION

For the foregoing reasons, the government requests the Court deny Defendant Holmes's motion.

DATED: July 9, 2020

Respectfully submitted,

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